



7/21

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q90669

Yoshifumi TAKENOBU, *et al.*

Appln. No.: 10/551,755

Group Art Unit: 1621

Confirmation No.: 1688

Examiner: Unknown

Filed: October 3, 2005

For: REMEDY FOR SPINAL CANAL STENOSIS

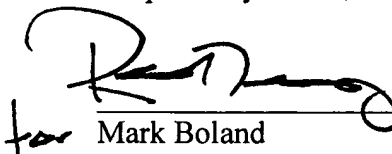
**SUBMISSION OF ENGLISH TRANSLATION OF
INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As stated in the new application transmittal letter filed October 3, 2005, it is assumed that a copy of the International Preliminary Examination Report (IPER) has been or will be supplied directly by the International Bureau. For the examiner's convenience, however, an English translation of the IPER (Form PCT/IB/338 and Form PCT/ISA/237) is submitted herewith.

Respectfully submitted,


for Mark Boland
Registration No. 32,197

REL NO.
47,125

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Enclosures: English translation of IPER (Form PCT/IB/338 and Form PCT/ISA/237)

Date: **AUG 29 2006**

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

OHIE, Kunihisa
Ohie Patent Office
Selva-Ningyocho 6F
14-6, Nihonbashi-Ningyocho
2-chome
Chuo-ku, Tokyo 103-0013
JAPON

'06.3.30

Date of mailing (day/month/year) 09 March 2006 (09.03.2006)	
Applicant's or agent's file reference ONF-4933PCT	IMPORTANT NOTIFICATION
International application No. PCT/JP2004/004836	International filing date (day/month/year) 02 April 2004 (02.04.2004)
Applicant ONO PHARMACEUTICAL CO., LTD. et al	

I. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
Facsimile No.+41 22 740 14 35	Facsimile No.+41 22 338 90 90

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference ONF-4933PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/JP2004/004836	International filing date (<i>day/month/year</i>) 02 April 2004 (02.04.2004)	Priority date (<i>day/month/year</i>) 03 April 2003 (03.04.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ONO PHARMACEUTICAL CO., LTD.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44bis.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 02 March 2006 (02.03.2006)
Facsimile No. +41 22 740 14 35	Authorized officer <div style="text-align: center; font-weight: bold; margin: 10px 0;">Yoshiko Kuwahara</div> Telephone No. +41 22 338 90 90

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

Translation

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

ONF-4933PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/004836

International filing date (day/month/year)

02.04.2004

Priority date (day/month/year)

03.04.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

ONO PHARMACEUTICAL CO., LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/004836

Box No. 1	Basis of this opinion
1.	<p>With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).</p>
2.	<p>With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:</p> <p>a. type of material</p> <p><input type="checkbox"/> a sequence listing</p> <p><input type="checkbox"/> table(s) related to the sequence listing</p> <p>b. format of material</p> <p><input type="checkbox"/> in written format</p> <p><input type="checkbox"/> in computer readable form</p> <p>c. time of filing/furnishing</p> <p><input type="checkbox"/> contained in the international application as filed.</p> <p><input type="checkbox"/> filed together with the international application in computer readable form.</p> <p><input type="checkbox"/> furnished subsequently to this Authority for the purposes of search.</p>
3.	<p><input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.</p>
4.	<p>Additional comments:</p>

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/004836

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 14

because:

☒ the said international application, or the said claims Nos. 14
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter described in claim 14 corresponds to a method for treatment of the human body by therapy (PCT Rule 67.1 (iv)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 14

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/004836

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-13, 15	YES
	Claims		NO
Inventive step (IS)	Claims	1-13, 15	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-13, 15	YES
	Claims		NO
2. Citations and explanations:	<p>The following documents were cited in the ISR:</p> <p>Document 1: Toshiaki Minami et al, Characterization of EP-receptor subtypes involved in allodynia and hyperalgesia induced by intrathecal administration of prostaglandin E₂ to mice, Br. J. Pharmacol, 1994, Vol. 112, p.735-740</p> <p>Document 2: EP, 860430, B1 (Ono Pharmaceutical Co., Ltd.), June 12, 2002 (12.06.02), full text</p> <p>Document 3: WO, 98-34916, A (Ono Pharmaceutical Co., Ltd.), August 13, 1998 (13.08.98), full text</p> <p>Document 1 describes the idea that the PGE₂ receptor subtypes EP2 and EP3 exist in the spinal cord, and the idea that PGE₂ triggers hyperalgesia in the spinal cord via those receptors.</p> <p>Document 2 describes the compound shown with the general formula (I) in the present international application.</p> <p>Document 3 describes the compound shown with the general formula (II) in the present international application.</p> <p>None of documents 1-3 describes or implies that the combination of a compound having an EP2 agonism and a compound having an EP2 agonism is applied for the purpose of preventing or treating spinal canal stenosis.</p> <p>Therefore, the subject matters of claims 1-13, 15 of the present international application appear to be novel and to involve an inventive step in view of documents 1-3.</p>		

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/004836

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-3, 7-13, 15 relate to spinal canal stenosis cures having compounds defined by the required property "EP2 agonism" or "EP3 agonism" as the active ingredient. And claims 1-3, 7-13, 15 include all compounds having such properties, but only a very small portion of the claimed compounds are supported by the description in the sense of PCT Article 6, and disclosed in the sense of PCT Article 5.

And for "a compound having EP2 agonism" or "a compound having EP3 agonism", no scope of compounds having such properties can be specified even when considering the common general technical knowledge at the time of the application. Therefore, claims 1-3, 7-13, 15 do not fulfill the requirement of clarity according to PCT Article 6.

BEST AVAILABLE COPY